United States Department of Agriculture
Food Safety And Inspection Service
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AUDIT REPORT FOR SPAIN

March 21 THROUGH April 5, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Spain's meat inspection system from March 21 through April 5, 2001. The four establishments certified to export meat to the United States were reviewed. All four establishments were conducting processing operations.

The last audit of the Spain's meat inspection system was conducted in June 2000. The same four establishments were reviewed.

The following were major concerns from the previous audit:

1. The HACCP plan did not adequately specify critical limit, monitoring procedures and monitoring frequencies performed for each CCP in Establishments 13, 14, 16, and 20. *Corrected.*

2. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed in Establishments 13, 14, 16, and 20. *Improvements were made but still inadequate.*

3. Corrective actions to be followed in response to a deviation from a critical limit were not addressed adequately in the written HACCP plan in Establishments 13, 14, and 20. *Corrected.*

4. Both establishment and inspection personnel had been unaware of the requirement for a final review of all documentation pertaining to the monitoring of critical limits for the product included in each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail; MSC ordered immediate implementation. *Corrected except Establishment 16*

5. MSC inspection officials were not adequately verifying the establishments' HACCP plan for monitoring critical control points, corrective actions, recordkeeping system and verification procedures. The auditor explained in detail; MSC indicated to implement such a system promptly. *Improvement was made but still inadequate.*

FSIS audited Spain's laboratory using equivalent EU Directives (EN 45001 guidelines), and that the previous issues comply with these equivalent guidelines (a, b, and c).

Spain exports only cured pork to the United States. Restrictions are placed on Spanish beef and fresh pork due to presence of foot and mouth disease, rinderpest, hog cholera and scrapie. Spain is considered to have a substantial risk associated with BSE and swine vesicular disease.

During the period of January 1 to December 31, 2000, Spanish establishments exported 589,907 pounds of cured pork to the U.S. Port-of-entry rejections were for Composition/ Standard (0.20 %). During the period of January 1 to February 28, 2001, Spanish establishments exported nearly 23,134 pounds of cured pork s to the U.S. There were no rejections at U.S. ports-of-entry.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Spanish national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed reviewing a selection of inspection records in Spain's meat inspection headquarters preceding the on-site visits. The third was an on-site visit to each exporting establishment. The fourth was an on-site visit to one government laboratory, which performs analytical testing of field samples for the national residue testing program and performs the presence of microbiological contamination with *Listeria*. The fifth was an on-site visit to autonomous government laboratory, which performs analytical testing of field samples for the national residue testing program and performs the presence of microbiological contamination with *Listeria, Salmonella* and *E.coli.*

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems, and (5) enforcement controls, including the testing program for *Salmonella* species and *listeria*. Spain's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

All four Establishments (13, 14, 16, and 20) certified to export to the United States were audited; one Establishment (Est.14) was judged Acceptable Subject to Re-review on the next audit. Three Establishments (13,16, and 20) were evaluated as acceptable.. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and *listeria* are discussed later in this report.
As stated above, five major concerns had been identified during the last audit of the Spanish meat inspection system, conducted in June 2000. Implementation of a Hazard Analysis-Critical Control Point (HACCP) programs were inadequate in Establishments 13, 14, 16, and 20. Monthly supervisory audits were not made as required by FSIS in Establishments 13, 14, 16, and 20.

During this new audit, the auditor determined that the major concerns had been addressed and improvements were made in Establishments 13, 14, 16, and 20. However, deficiencies regarding implementation of the required HACCP programs still exist in the four establishments visited (Ests. 13, 14, 16, and 20). Details are provided in the Slaughter/ Processing Controls section later in this report.

Entrance Meeting

On March 21, 2001, an entrance meeting was held in the Madrid office of the Ministerio De Sanidad Y Consumo (MSC), and was attended by Dr. Oscar Gonzalez Gutierrez Solana, Subdirector General de Sanidad Exterior y Veterinaria; Dr. Jesus Martin Ruiz, Jefe de Area de Veterinaria de Salud Publica; Dr. Margarita Garzon Rigau, Jefe de Servicio Veterinaria Oficial; Dr. Sonsoles Sanchez, Jefe de Area, Ministerio de Agricultura; Mr. Mario Carbajo, Interpretor; Mr. Diego Pazos Moran, Senior Agricultural Specialist, American Embassy; and Dr. Faiz R. Choudry, International Audit Staff Officer, FSIS. Topics of discussion included the following:

- Itinerary and lodging arrangements for the auditor were finalized.
- The auditor shared with the MSC officials the updated data collection instruments for HACCP, *Salmonella* testing, and SSOPs.
- Residue Questionnaire for Spain was discussed.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Spain’s inspection system in June, 2000.

Prior to the on-site audits of establishments, certain central documents were examined in the office of the meat/poultry inspection headquarters, including the results of the 2000 national residue testing program and the 2001 residue testing plan

- Training records for inspectors and laboratory personnel.

- New laws and implementation documents such as regulations, notices, directives and guidelines.

- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs.

- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the reviews of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor observed and evaluated the process.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Spain as eligible to export meat products to the United States were full-time either MSC or Autonomous Government Public-Health employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Four establishments were certified to export meat products to the United States at the time this audit was conducted. All four establishments (13, 14, 16, and 20) were reviewed. In all four establishments, adequate MSC inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. These three establishments were found acceptable. One establishment (Est. 14) was rated acceptable subject to re-review on the next audit because of several deficiencies regarding sanitation and condition of facilities.

Laboratory Audits

FSIS audited Spain's laboratory using equivalent EU Directive (EN 45001 guidelines).

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about

the risk areas of government oversight of accredited, approved, and private laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The Institute De Salud Carlos 111, Centro Nacional De Alimentacion Laboratory in Ctra. Majadahonda was audited on March 23, 2001.

Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, check sample frequency, and corrective actions. The methods used for the analyses were acceptable

Spain's microbiological testing program for *Salmonella* and *E.coli* was being performed in the autonomous Gobierno de La Rioja laboratory at the Laboratorio Regional. Consejeria de Agricultura, Ganaderia y Desarrollo Rural in Logrono, was visited on March 30, 2001. Dr. Jose Antonio Garcia Morras is the director at this laboratory. This laboratory is not performing *Salmonella* and *E.coli* testing under FSIS' Pathogen Reduction/HACCP rule but *E.coli* testing is being performed for water and other food products and *Salmonella* for different ready-to-eat products. This laboratory meets the following criteria:

- The laboratory was accredited in May 28, 1999 by Entidad Nacional de Acreditacion (ENAC)/approved by the government.

- The laboratory had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.

- Results of analyses were being reported to the government or simultaneously to the government and establishment.

- The autonomous government laboratory uses analytical methods for *Salmonella* (Met/BA/Alim y agua/1), and *E.coli* (Met/BA/Alimentos/4) under the Norma EN 45001-89; UNE 66-501-91 y Guia ISO 25-90

Establishment Operations by Establishment Number

The following operations were being conducted in the four establishments:

Cured/dried pork products - three establishments (13, 14, and 20)
Cured/dried chorizos – one establishment (16)

SANITATION CONTROLS

Based on the on-site audits of establishments, Spain's inspection system had controls in place for water potability records; chlorination procedures; back–siphonage prevention; hand washing facilities; sanitizers; separation of operations; pest control and monitoring; temperature control; lighting; work space; ventilation; maintenance and cleaning of over-

product ceilings and equipment; dry storage areas; personal dress, habits, and hygiene; equipment sanitizing; and product handling and storage.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

Basic Establishment Facilities

- The facility for sanitizing knife in the processing room was designed in such a way that it was not possible to sanitize knife completely and effectively in Establishment 20. *Establishment officials ordered correction.*

Condition of Facilities and Equipment

- Overhead beams and ceilings in the pre-boning cooler over exposed edible product were observed with rust and flaking paint in Establishment 14. *Establishment officials ordered correction immediately.*

- A few working table bottoms and frames for edible product that were not in use but ready for use, in the ham curing and de-boning rooms were found with grease, fat, and black discoloration in Establishment 14. *Establishment officials ordered correction immediately.*

- Band saw, that was not in use but ready for use, in the processing room was found with dried fat and old pieces of meat from previous days' production in Establishment 20. *Establishment officials ordered correction immediately.*

Cross-Contamination

- Dripping condensate from overhead refrigeration units and pipes that were not cleaned/sanitized was falling onto exposed edible product in the ham de-boning room in Establishment 14. *Neither establishment nor meat inspection officials took corrective action.*

- One employee was observed picking up pieces of strings from the floor and, without washing his hands, handling edible product in the pre-de-boning room in Establishment 14. *Neither establishment nor meat inspection officials took corrective action.*

- An other employee was observed picking up steel from the floor and, without washing his hands or sanitizing his steel, handling edible product in the boning room in Establishment 16. *Neither establishment nor meat inspection officials took corrective action.*

Potential for Cross Contamination

- Hams were contacting employees' working platform at the pre de-boning station in Establishment 14. *Establishment officials took corrective action temporarily and proposed modification to prevent recurrence to GOS inspection officials.*

Reconditioning of contaminated Product

- No facility was provided for dropped ham to be reconditioned in a sanitary manner in the processing room in Establishment 14. *Establishment officials ordered correction immediately.*

ANIMAL DISEASE CONTROLS

Spain's inspection system had controls in place to ensure adequate product identification, restricted product control, and procedures for sanitary handling of returned and rework product. Spain does not have any approved slaughter establishments for export to the United States. All hog carcasses or hams used for exported product to the United States are imported from Denmark and Netherlands. Spain's inspection system had adequate controls in place to ensure control over the above areas, with the following deficiencies. The auditor's findings are presented below for the area of animal disease.

- Containers for edible and inedible product were not identified in the processing room and condemned product was not properly identified and denatured in Establishments 13 and 14. *Establishment officials ordered correction immediately.*

- Containers for edible and inedible product were not identified in the boning and processing rooms in Establishment 16. *Establishment officials ordered correction immediately.*

- Condemned product was not denatured in Establishment 20. *Establishment officials ordered correction immediately.*

No outbreaks of animal diseases with public-health significance have been reported since the previous U.S. audit. At the time of audit, Spain had thirty positive cases for Bovine Spongiform Encephalopathy (BSE) and no positive case was found for Foot and Mouth Disease. Spain is considered to have a substantial risk associated with BSE and Swine Vesicular Disease. APHIS has not declared Spain free of Foot and Mouth Disease, Rinderpest, Hog cholera, and Scrapie.

Farm Visit

Mr. Jose Luis Garcia Ferrero' farm (Selecciones Porcinas, S. A, Finca Quinto del Encinar) located in Santa Cruz del Retamar (Toledo) was visited on April 3, 2001. It was a small

swine breeding farm on a sixty hector land with about 1500 sows, boar including market hogs.

A full time private veterinarian makes the diagnosis, prescription and administers the drugs for treatment. Animals are identified by a single earmark, which identifies the farm, as well as a tattooing mark before leaving farm, the month of the birth of the animal and the code for the farm (premises). Medicated feeds are given to sows, boars and young pigs or breeding stock that will not be going to slaughter in the next 75 days. The farm is required to analyze one sample of medicated feed each year to demonstrate the medicated feed is incompliance. Medicated and non-medicated feed combos are separate.

The swine farm that was visited is licensed to store animal drugs on site. Farms must be specifically approved to store animal drugs on the premises. On those farms which are not approved to store drugs, the veterinarian may only prescribe drugs in amounts that can be used immediately. Records are maintained on all animal drugs requiring prescription, which are written in triplicate so that copies can be maintained by the prescribing veterinarian, filed at the farm, provided to the District where the farm is located and provided to the pharmacy/ wholesaler dispensing the drug. The autonomous government veterinarian and sometime even local police cross checks and verify all the prescriptions written or dispensed in the District.

Certificates (affidavits) are issued for every group of animals moving off of the farm, whether to another farm or to slaughter. Any drugs applied to animals within 75 days of slaughter will be recorded on the transportation documents, with a copy of the prescription attached. Drug inventory and use records are maintained and all drugs are controlled in a locked cabinet or refrigerator.

On-site visits by the autonomous veterinarian are scheduled annually to review the record keeping for veterinarian drug use and checks on feedstuffs. The autonomous government schedules on-farm sampling of animals for drug residue at random basis. No samples are scheduled or collected from live animals under this plan in this farm.

The National Program for Residue Control is based on European Community legislation in force related to the ban of hormonal substances (Council Directive 96/22/EC April 1996) and the control of residues on live animals and animal products (Council Directive 96/23/EC of April 1996). These directives have been transposed into Spanish law through the Royal Decree No. 1749 in 1998.

Reporting Positive Results

Though no violations had occurred at the farm visited, the Regional authorities confirmed that violations are followed up on a case-by-case approach depending upon the substance in question. At the farm, the autonomous government will increase inspections but may not take a sample every time. Intensified sampling is statistically based, and if over half of the samples are positive, the entire herd will be destroyed. If the substance is prohibited, there are criminal sanctions resulting in arrest and possible fines/jail.

RESIDUE CONTROLS

Spain's National Residue Testing Plan for 2001 was being followed, and was on schedule. The Spanish inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The Spanish inspection system had controls in place to ensure adequate pre-boning trim, ingredients identification, control of restricted ingredients, formulations, packaging materials, processing schedules, processing equipment, and processing records.

Spain does not have any approved slaughter establishment for export to the United States.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system equivalent to that of the United States. Each establishment's HACCP system was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were audited and found to meet the basic FSIS regulatory requirements with the following exceptions:

- The HACCP plan did not adequately state the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed in Establishments 13, 14, 16, and 20. *Establishments officials indicated that it would be corrected immediately.*

- MSC inspection officials were not adequately verifying the establishments' HACCP plan for monitoring critical control points, and plant verification procedures in Establishments 13, 14, and 16. *MSC officials indicated that it would be corrected immediately.*

- Corrective actions were not taken in response to a deviation from a critical limit as addressed in the written HACCP plan in Establishments 14. *Establishment officials indicated that it would be corrected immediately.*

- Establishment verification was inadequate, for a final review of all documentation pertaining to the monitoring of critical limits for the product included in each shipment before that shipment leaves the establishment in Establishment 16. *Establishment officials indicated that it would be corrected immediately.*

- The Ministerio de Sanidad y Consumo (MSC) and Autonomus Government Public Health inspection officials did not have formal HACCP training. *The GOS inspection*

officials indicated that they did not have enough manpower to release officials for HACCP training.

Testing for Generic *E. coli*

All four establishments were not required to meet the basic FSIS regulatory requirements for generic *E. coli* testing because none of the establishment slaughtered meat for export to the United States. All hams intended for export to the United States were imported from Denmark and Netherlands from slaughter establishments approved to export to the United States. Hog carcasses and/or hams received from domestic slaughter establishments were used for Spanish domestic consumption and/or exported to EU countries.

Additionally, establishments had adequate controls in place to prevent meat products intended for Spanish domestic consumption from being commingled with products eligible for export to the United States.

Control of *Listeria monocytogenes*

In response to the auditor's inquiry regarding the Spanish establishment officials' evaluation of their HACCP programs to address the risk of *Listeria monocytogenes*, the meat inspection officials provided this information. All four establishments either 1) did not conduct a hazard analysis for *Listeria monocytogenes* to determine the food safety hazards reasonably likely to occur in the production process for ready-to-eat products, or 2) did not have scientific evidence to demonstrate that controls were not needed.

Establishment 14 voluntarily initiated four *Listeria monocytogenes* samples every fifteen days for ready-to eat (RTE) product and ten samples every fifteen days for environment contamination. All product from Establishment 13 is shipped to Establishment 14 for further processing and *Listeria monocytogenes* controls. Establishment 20 is planing to initiate *Listeria monocytogenes* sampling voluntarily in the near future. Establishment 16 was taking six samples voluntarily for each *Listeria monocytogenes* and *salmonella* for ready-to-eat products.

MSC meat inspection officials were taking one sample per month from each establishment for *Listeria monocytogenes* testing on raw product only.

ENFORCEMENT CONTROLS

Inspection System Controls

The MSC inspection system controls [control of restricted product and inspection samples, processed meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls, inspection supervision, and documentation, and the importation of only eligible meat products from

other counties (i.e., only from eligible countries and certified establishments within those countries), for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

None of the four establishments reviewed was required to meet the basic FSIS regulatory requirements for *Salmonella* testing because none slaughtered meat for export to the United States. Establishments 13, 14, and 20 were producing dry-cured hams and Establishment 16 was producing dry-cured chorizos. *Salmonella* testing was being conducted on ready-to-eat products in Establishments 14 and 16.

Species Verification Testing

At the time of this audit, Spain was not exempt from the species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

The internal audits in Spain were being conducted in three parts as follows:

A) Federal Government; two audits per year by Drs. Margarita Garzon and Julio Navarro, both of whom were veterinarians in the Ministerio de Sanidad y Consumo, under the direct supervision of the Subdirector General de Sanidad Exterior y Veterinaria, Dr. Oscar Gonzalez Gutierrez Solana.

No specific method was used for selecting the review dates of the establishments, but the dates varied from year to year. The internal audit program was applied only to export establishments. The internal audits were conducted once a year, and were announced to the inspection personnel about two weeks in advance. Copy of each internal audit report was kept in the headquarters of the Ministerio de Sanidad y Consumo in Madrid.

B) Autonomus Government Public Health, one audit per year by a staff veterinarian during any time of the year. A copy of the audit report was kept in the Autonomus Government Public Health office and also in the establishment.

C) Provincial Government, ten audits per year by a staff veterinarian. No specific method was used for selecting the review dates of the establishments, but the dates varied from each audit. One copy of each internal audit report was kept in the Provincial headquarters and also in the establishments. They were being maintained on file for a minimum of 3 years.

The internal review program was applied only to export establishments. The internal audits were conducted mostly once in two months, and were announced to the inspection personnel, about two weeks in advance; the establishment officials were not informed in advance. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the provincial office.

If an establishment failed to comply with U.S. requirements during an internal audit, it would be immediately delisted for U.S. export. Before it may again qualify for eligibility to be reinstated, MSC meat inspection officials are empowered to conduct an in-depth review, and the results are reported to Dr. Oscar Gonzalez Gutierrez Solana, Subdirector General de Sanidad Exterior y Veterinaria, for evaluation. He would formulate a plan for corrective actions and preventive measures.

Enforcement Activities

Dr. Oscar Gonzalez Gutierrez Solana, Subdirector General, MSC, indicated that Royal Decree 1904/1993 is Spain's legislation to enforce noncompliance when an establishment had not met the regulatory requirements. Under this decree, MSC may temporarily withhold the marks of inspection from specific products, suspend inspection, or withdraw a grant of inspection if an establishment is not meeting crucial requirements.

Exit Meetings

An exit meeting was conducted in Madrid on April 4, 2001. The participants were Dr. Oscar Gonzalez Gutierrez-Solana, Subdirector General de Sanidad Exterior y Veterinaria, MSC; Dr. Margarita Garzon Rigau, Jefe de Servicio Veterinaria Oficial; Dr. Jose L. Paramio Lucas, Jefe de Area, Ministerio de Agricultura; Dr. Juan Jose Martinez, Autonomous Government Public Health Logrono; Dr. Visitacion Cortes Ibanez, Autonomous Government Public Health Vallencia; Mrs. Julia Navardro Pedales, Tecnico, MSC; Dr. Antonio Garcia Jane, Jafe de Seccion de Hygiene Alimentaria, Autonomous Government Castilla-La Mancha; Dr. Jose Juan Sanchez Saez, Subdirector General Laboratory (CAN); Dr. Fernando Tovar, Director General (CNL); Mr. Mario Carbajo, Interpretor; Mr. Diego Pazos Moran, Senior Agricultural Specialist, American Embassy; and Dr. Faiz R. Choudry, International Audit Staff Officer, FSIS.

The deficiencies identified were discussed in detail. Dr. Oscar Gonzalez Gutierrez-Solana reinforced the assurances made by the field personnel during and at the conclusions of the on-site reviews of each establishment, and stated that they would ensure prompt compliance with FSIS import requirements.

A second meeting was conducted with European Commission (EC) in Brussels, Belgium on April 5, 2001. The EC participants were Dr. Paolo M. Drostby, EC Expert, Unit E-3, Health and Consumer Protection Directorate-General; Dr. Thomas Eoin Golden, Principal Administrator, Unit D-2 (Biological Risks), Directorate D, Health and Consumer Protection Directorate-General; Ms. Melinda Sallyards, Agricultural Attaché, United States Mission to

the European Union in Brussels; and Dr. Faiz R. Choudry, International audit Staff Officer, FSIS.

During this meeting, the deficiencies listed below were discussed in detail. Dr. Oscar Gonzalez Gutierrez-Solana, Subdirector General de Sanidad Exterior y Veterinaria, MSC, indicated that the Government of Spain would take the necessary steps to ensure that corrective actions and preventive measures, as promised during the audits and exit meetings in the individual establishments, would be implemented.

- The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed (Establishments 13, 14, 16, and 20).

- MSC inspection officials were not adequately verifying the establishments' HACCP plan for monitoring critical control points, and plant verification procedures (Establishments 13, 14, and 16).

- Corrective actions were not taken in response to a deviation from a critical limit as addressed in the written HACCP plan (Establishments 14).

- Establishment verification was inadequate for a final review of all documentation pertaining to the monitoring of critical limits for the product included in each shipment before it leaves the establishment (Establishment 16).

- Equipment in contact with product such as working tables and band saws, that were not in use but ready for use, in the ham curing and de-boning rooms and processing rooms were found with grease, fat, and black discoloration, dried fat and old pieces of meat (Establishment 14, and 20).

- Cross contamination and insanitary handling of product were observed in Establishments 14 and 16 such as: a) dripping condensate from overhead refrigeration units and pipes that were not cleaned/sanitized daily, was falling onto exposed edible product in the ham boning room; b) one employee was observed picking up pieces of strings from the floor and, without washing his hands, handling edible product in the pre de-boning room; and c) an other employee was observed picking up steel from the floor and, without washing his hands or sanitizing his steel, handling edible product in the boning room.

- Potential for cross contamination of product such as hams was contacting employees' working platform at the pre-de-boning station in Establishment 14.

- Reconditioning of contaminated product such as facility for dropped ham to be reconditioned in a sanitary manner was not provided in the processing room in Establishment 14.

- Basic establishment facility for sanitizing knife in the processing room was designed in such a way that it was not possible to sanitize knife completely and effectively in Establishment 20.

- Containers for edible and inedible product were not identified in Establishments 13, 14, and 16. Condemned product was not properly identified and denatured in Establishment 13, 14, and 20.

CONCLUSION

Four establishments were reviewed: three were acceptable and one was evaluated as acceptable/re-review. The deficiencies encountered during the on-site establishment reviews were adequately addressed to the auditor's satisfaction. The GOS meat inspection officials reinforced the assurances made by the field personnel during and at the conclusions of the on-site reviews of each establishment and stated that they would ensure prompt compliance.

The establishments have made considerable improvements in the implementation of written SSOPs and HACCP programs. However, deficiencies in these areas still exist and, therefore, additional work is needed to fully comply with FSIS requirements.

The Ministerio de Sanidad y Consumo (MSC) and Autonomus Government Public Health inspection officials did not have formal HACCP training. The GOS inspection officials indicated that they did not have enough manpower to release officials for HACCP training.

Dr. Faizur R. Choudry
International Audit Staff Officer

(signed)Dr. Faizur R. Choudry

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing *(not applicable)*
D. Data collection instrument for *Salmonella* testing *(not applicable)*
E. Laboratory Audit Forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
13	√	√	√	√	√	√	√	√
14	√	√	√	√	√	√	√	√
16	√	√	√	√	√	√	√	√
20	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis	3. All hazards ident-ified	4. Use & users includ-ed	5. Plan for each hazard	6. CCPs for all hazards	7. Mon-itorin g is spec-ified	8. Corr. actions are des-cribed	9. Plan valida-ted	10.Ade-quate verific. Proced-ures	11.Ade-quate docu-mentation	12. Dated and signed
13	√	√	√	√	√	√	√1	√	√	√3	√	√
14	√	√	√	√	√	√	√	√2	√	√	√	√
16	√	√	√	√	√	√	√	√	√	√3	√	√
20	√	√	√	√	√	√	√	√	√	√3	√	√